UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte HENRY YUE, Y.TOM TANG,
JENNIFER L. HILLMAN, PREETI LAL,
OLGA BANDMAN, MARIAH R. BAUGHN,
YALDA AZIMZAI, JUNMING YANG,
ROOPA REDDY, and DYUNG AINA M. LU

Appeal No. 2004-2310
Application No. 10/018,170

ORDER UNDER 37 CFR § 41.50(d)

Before SCHEINER, GRIMES and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

ORDER UNDER 37 CFR § 41.50(d)

Under the provisions of 37 CFR § 41.50(d),[1] we require Appellants to address the following matters:

First, we invite attention to commonly assigned Application No. 09/209,859 where, according to Patent and Trademark Office (PTO) records, the applicants filed a Notice of Appeal from the examiner's final rejection on April 27, 2001. After a briefing stage and oral hearing on February 21, 2003, another panel of the Board handed down

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[1] "The Board may order appellant to additionally brief any matter that the Board considers to be of assistance in reaching a reasoned decision on the pending appeal. Appellant will be given a non-extendable time period within which to respond to such an order." 37 CFR § 41.50(d).

its decision in the '859 application, affirming the examiner's final rejection of claims 1 and 11 (Appeal No. 2002-0774, BPAI 2003).

We think it clear that Appeal No. 2002-0774, in Application No. 09/209,859, bears close relationship to the instant appeal. In Appeal No. 2002-0774, the claims are drawn to a substantially purified polypeptide, viz., a transmembrane protein designated ONMO having the amino acid sequence shown in SEQ ID NO:1; as well as naturally occurring variants and biologically active fragments thereof, and pharmaceutical compositions comprising any of those polypeptides in conjunction with a pharmaceutical carrier. The sole issue presented was whether the applicants' claims were supported by a disclosure of utility sufficient to satisfy 35 U.S.C. § 101.

In what the previous panel referred to as "a second line of argument" or "a second line of reasoning," the applicants argued that their claimed polypeptides have utility because all expressed human genes and polypeptides have utility as research tools (Application No. 09/209,859, Paper No. 28, page 9, lines 3 through 5; and paragraph bridging pages 10 and 11). The applicants reasoned that the technique of expression profiling, in which the expression of numerous genes is compared in two or more samples, is used in research relating to toxicology testing, drug development, and disease diagnosis; that "[g]enes or gene fragments known to be expressed, such as the invention at issue, are tools essential to any technology that uses expression profiling;" that "[t]he more genes that are available for use in toxicology testing, the more powerful the technique;" and that "there is no expressed gene which is irrelevant to screening for toxicological effects, and all expressed genes have a utility for toxicological screening.

This is true for both polynucleotides and polypeptides encoded by them." Id., paragraph bridging pages 10 and 11.

Additionally, the applicants argued before the previous merits panel that "[as] used in toxicology testing, drug discovery, and disease diagnosis, the claimed invention has a beneficial use in research other than studying the claimed invention . . . It is a tool, rather than an object, of research." According to the applicants, this distinguished their case from reported cases like Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), and In re Kirk, 376 F.2d 936, 153 USPQ 48 (CCPA 1967), where "the only known use for the claimed invention [was] to be an object of further study." Id., page 11, first full paragraph.

The applicants also argued that § 101 is satisfied by utilities that apply equally to all expressed human genes and proteins; the utility need not be "particular" to the claimed invention. "Practical real-world uses are not limited to uses that are unique to an invention." Id., page 12, second full paragraph.

The previous merits panel reviewed governing principles of law; addressed and rejected the applicants' "second line of argument;" and concluded that "Appellants' disclosure in th[at] case does not provide a specific benefit in currently available form, and therefore lacks the substantial utility required by 35 U.S.C. § 101." Id., page 31, lines 2-4. Accordingly, the examiner's decision, rejecting claims 1 and 11 in Application No. 09/209,859, was affirmed.

Like the claims in Application No. 09/209,859, the claims in this appeal are drawn to, among other things, an isolated polypeptide and an isolated polynucleotide encoding the polypeptide. All of the appealed claims stand rejected under 35 U.S.C.

§ 101 "because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility" (Examiner's Answer, page 4).

The Appeal Brief in this appeal includes essentially the same "second line of argument" addressed by the previous merits panel in Appeal No. 2002-0774 (Appeal Brief, section (9)).[2] For example, Appellants argue that "[t]he use of polynucleotides and polype[p]tides expressed by humans as tools for toxicology testing, drug discovery, and the diagnosis of disease is now 'well-established'" (id., page 15); that "[t]he more genes that are available for use in toxicology testing, the more powerful the technique. . . . Thus, there is no expressed gene which is irrelevant to screening for toxicological effects, and all expressed genes have a utility for toxicological screening" (id., page 16); that "[t]he claimed invention is a tool, rather than an object, of research" (id., page 25); that "[o]ver the past several years, a vibrant market has developed for databases containing all expressed genes (along with the polypeptide translations of those genes). . . . (Note that while the value in these databases is enhanced by their completeness, each sequence in them is independently valuable nonetheless.)" (id., page 20); and that "broad classes of inventions can satisfy the utility requirement so long as a person of ordinary skill in the art would understand how to achieve a practical benefit from knowledge of the class" (id., page 27).

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[2] We note that the evidence of record in this appeal differs from that of 2002-0774, in that the examiner in this case has entered and responded to Appellants' declaratory evidence. However, the panel in 2002-0774 "assum[ed] arguendo that the use of polypeptides to monitor gene expression in research related to toxicology testing, drug development, and disease diagnosis was well-established as [of] the application's filing date." Application No. 09/209,859, Paper No. 28, page 14. The panel then went on to explain in detail why Appellants' "expression profiling" argument was unconvincing, even assuming it was supported by evidence. See id., pages 14-31. Since the Bedilion and Furness declarations in this case appear to be directed to providing evidence in support of the same "expression profiling" argument, the panel's analysis in 2002-0774 appears to be equally applicable to this case.

On these facts, we require that Appellants explain why we should address anew the "second line of argument" in this case. Respecting the issue raised by the "second line of argument," that same issue having been raised previously in Appeal No. 2002-0774, why would the previous panel's treatment of that issue not be dispositive here? In particular, why should the facts and arguments set forth in Appellants' Appeal Brief lead to a different conclusion than that reached by another panel in Appeal No. 2002-0774 rejecting the same "second line of argument?"

We note that the applicants did not request rehearing on the same record within two months from the date of the decision in Appeal No. 2002-0774. Rather, according to PTO records, the applicants elected to have the matter reconsidered by the examiner on a different record. See 37 CFR § 1.196(b) (now 37 CFR § 41.50(b)). We also note that the U.S. Court of Appeals for the Federal Circuit has since approved reasoning similar to that relied on in Appeal No. 2002-0774. See In re Fisher, 421 F.3d 1365, 76 USPQ2d 1225 (Fed. Cir. 2005).

Second, Appellants state that "[t]he claimed invention has specific, substantial, real-world utility by virtue of its use in toxicology testing, drug development and disease diagnosis through gene expression profiling. . . . There is no dispute that the claimed polynucleotide is in fact a useful tool in cDNA microarrays used to perform gene expression analysis and that the claimed polypeptide is a useful tool in two-dimensional polyacrylamide gel electrophoresis ('2-D PAGE') analysis and western blots used to monitor protein expression and assess drug toxicity." Appeal Brief, page 10.

However, the assertion that "[t]here is no dispute that the claimed invention is in fact a useful tool" appears to be incorrect. See, e.g., the Examiner's Answer at page

10:

> [A]ny polynucleotide can be used in a microarray. This utility is not specific to the claimed invention. In this case, the specification fails to provide evidence that SEQ ID NO:64 or the polypeptide encoded thereby is a target for drug development, toxicology studies, or disease diagnosis. Furthermore, the specification fails to provide guidance for using the claimed compounds for drug development, toxicology studies, or disease diagnosis, e.g., how a skilled artisan would use data relating to the claimed polynucleotide derived from the results of gene expression analysis and what the results would mean.

Thus, it appears that there is a dispute regarding whether claimed polypeptide or polynucleotide have patentable utility because they can be used to monitor gene expression. Explanation or clarification of this apparent discrepancy is required.

Conclusion

In conclusion, we require Appellants to address the foregoing matters "consider[ed] to be of assistance in reaching a reasoned decision on the pending appeal." 37 CFR § 41.50(d). We caution, however, that this is not an invitation to expand on points raised in the Appellants' brief or to rehash arguments already set forth in the brief. This is not an invitation to raise arguments or issues on appeal, or to collaterally attack the decision in Appeal No. 2002-0774. See 37 CFR § 41.37(c)(1)(vii) ("Any arguments or authorities not included in the brief or a reply brief filed pursuant to § 41.41 will be refused consideration by the Board, unless good cause is shown"). Appellants' response should be confined to the matters outlined above.

Time Period For Response

A period of one month from the date of this order is set for Appellants' response. This time is non-extendable.

Failure to respond in a timely manner will result in dismissal of the appeal.

37 CFR § 41.50(d)

Toni R. Scheiner)
Administrative Patent Judge)
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Eric Grimes) BOARD OF PATENT
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